JUN 1 0 2011

510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k111023.

Applicant Name:

John Rizos, Senior Regulatory Affairs Administrator
Regulatory Affairs
Abbott Laboratories Diagnostics Division
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Device Name:

Classification Name: Calibrator, Secondary
Trade Name: ARCHITECT LH Calibrators
Common Name: Human Luteinizing Hormone
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Legally marketed device to which equivalency is claimed:

Abbott ARCHITECT LH Calibrators (List No. 7G94-01), k032458

Intended Use of Device:

The ARCHITECT LH Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of human luteinizing hormone (LH) in human serum and plasma.

Description of Device:

The ARCHITECT LH Calibrator kit contains 6 bottles (4.0 mL each) of ARCHITECT LH Calibrators A, B, C, D, E, and F. Calibrators A through F contain phosphate buffer with protein (bovine) stabilizers. Calibrators B through F also contain different concentration levels of luteinizing hormone (from human pituitary). Preservatives: ProClin 300, ProClin 950.

Comparison Table:

The table below compares the new device, ARCHITECT LH Calibrators, List No. 2P40-01, with the predicate device, ARCHITECT LH Calibrators, List No. 7G94-01 (k032458).

Comparison of New Device to Predicate Device		
Attribute	**Predicate Device ARCHITECT LH Calibrators List No. 7G94-01, k032458**	**New Device ARCHITECT LH Calibrators List No. 2P40-01**
Intended Use	For the calibration of the ARCHITECT *i* System when used for the quantitative determination of human luteinizing hormone (LH) in human serum and plasma.	Same
Instrumentation	ARCHITECT *i* System	Same
Range	2 mIU/mL – 100 mIU/mL	0.00 mIU/mL – 250.00 mIU/mL
LH Calibrators	• 2 levels • 2 and 100 mIU/mL human luteinizing hormone • Calibrators must be used with matched reagents and controls per labeling.	• 6 levels • 0.00, 1.00, 3.50, 15.00, 50.00, 250.00 mIU/mL human luteinizing hormone • Note: Matching of calibrators with reagents and controls is not required.
Composition	• Calibrators 1-2: Luteinizing hormone (from human pituitary) • Calibrators 1-2: Diluent: Calf serum • Calibrators 1-2: Preservative: Sodium Azide	• Calibrators B-F: Luteinizing hormone (from human pituitary) - changed vendor code • Calibrators A-F: Diluent: Phosphate buffer with protein stabilizers (bovine) • Calibrators A-F: Preservatives: ProClin 300, ProClin 950

Comparison of New Device to Predicate Device		
Attribute	**Predicate Device ARCHITECT LH Calibrators List No. 7G94-01, k032458**	**New Device ARCHITECT LH Calibrators List No. 2P40-01**
Standardization	The calibrators are manufactured by dilution and referenced to the World Health Organization (W.H.O.) Luteinizing Hormone (LH) Human, Pituitary 2nd International Standard 80/552 at each Concentration.	The calibrators are referenced to the World Health Organization (WHO) Luteinizing Hormone (LH) Human, Pituitary 2nd International Standard 80/552. Note: Calibrators B-F are manufactured by dilution.

Conclusion:

Substantial equivalence for the new device, ARCHITECT LH Calibrators (List No. 2P40-01), is claimed to the predicate device cleared in k032458, ARCHITECT LH Calibrators (List No. 7G94-01), based on the information described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Abbott Laboratories
c/o Mr. John Rizos
Senior Regulatory Affairs Administrator
100 Abbott Park Road
Department 9V6, AP5N-2
Abbott Park, IL 60064

JUN 10 2011

Re: k111023
Trade Name: Architect LH Calibrators
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT
Dated: April 12, 2011
Received: April 19, 2011

Dear Mr. Rizos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k111023

Device Name: ARCHITECT LH Calibrators

Indications for Use

The ARCHITECT LH Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of human luteinizing hormone (LH) in human serum and plasma.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k111023